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EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/813,225

Applicant(s)

ORR ET AL.

Examiner

Patricia C. Mallari

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-120 is/are pending in the application.
- 4a) Of the above claim(s) 1-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-120 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3.5
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Election/Restrictions

In light of the applicants' comments in paper No. 7, filed 4/24/03, with respect to the Election of Species Requirement, it seems that the requirement, as presented in paper No. 6, filed 3/20/03, was improper. That requirement has been removed and replaced by the following Restriction Requirement.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-33, drawn to a rebreathing method, consisting essentially of effecting a nonrebreathing period and a rebreathing period, classified in class 600, subclass 529.
- II. Claims 34-120, drawn to a method or Fick technique of estimating pulmonary capillary blood flow or cardiac output of a patient, classified in class 600, subclass 526.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because any ventilation state or change in ventilation, other than a rebreathing method, may be used. The subcombination has separate utility such as merely changing the breathing of a patient.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Brick Power on February 23, 2004 a provisional election was made without traverse to prosecute the invention of Invention II, claims 34-120. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 42 recites a method having the limitation "wherein said evaluating respiration during said first ventilation state comprises bi-directional rebreathing", where, according to claim 34, upon which claim 42 depends, the method also comprises evaluating respiration during a second ventilation state. According to pp. 15-16, paragraph 0061 of the specification, a bi-directional rebreathing method consists of

measuring respiratory parameters in each of a “before,” “during” and “after rebreathing phase. However, the specification fails to provide sufficient antecedent basis of a method comprising the steps of evaluating respiration during a before, during, and after rebreathing phase, and evaluating respiration in a second ventilation state.

Similarly, claim 61 recites the limitation “ wherein said evaluating respiration of the patient during said first ventilation state comprises bi-directional rebreathing”. However, the specification fails to provide sufficient antecedent basis for a method comprising a step of evaluating respiration during each of a before, during, and after rebreathing phase (bi-directional rebreathing method), a step of evaluating the respiration of a patient during a second ventilation state immediately following the bi-directional rebreathing method, and another step of bi-directional rebreathing.

Claim Objections

Claim 54 is objected to because of the following informalities: on line 2 of the claim “another first ventilation state” should be replaced with “said another first ventilation state”. Appropriate correction is required.

Claim 57 is objected to because of the following informalities: on line 2 of the claim, “another first ventilation state” should be replaced with “said another first ventilation state”. Appropriate correction is required.

Claim 113 is objected to because of the following informalities: on line 1 of the claim “said evaluatings” should be replaced with “said step of evaluating respiration during a first phase and said step of evaluating respiration following removal of said change”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-120 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 recites in the preamble “a method for noninvasively estimating at least one of a pulmonary capillary blood flow and a cardiac output of a patient” but fails to recite steps that actually estimate either of pulmonary blood flow or cardiac output.

Claim 47 recites the limitation “wherein said evaluating respiration of the patient during said second ventilation state is effected before initiation of the noninvasively estimating.” In claim 34, “noninvasively estimating” is disclosed as a method comprising a step of “evaluating respiration of the patient during said second ventilation state”. It is unclear how the recited step of the method may be effected before initiation of the method.

Claim 52 recites the limitation “a method for noninvasively estimating at least one of a pulmonary capillary blood flow and a cardiac output of a patient” but fails to recite steps that actually estimate either of pulmonary blood flow or cardiac output.

Claims 70 and 84 recite the limitation “a differential Fick technique”, and claims 71-83 and 85-99 recite the limitation “the differential Fick technique” on line 1 of each claim. Although the instant specification discusses a differential Fick technique for determining cardiac output or pulmonary capillary blood flow of a patient, the preamble

of these claims fail to distinctly point out the aim of the claimed technique, thereby rendering it indefinite. Furthermore, the claims fail to delineate any step of actually determining either the pulmonary capillary blood flow or cardiac output.

Claim 78 recites the limitation "wherein the second phase occurs before said first phase". However, claim 70, upon which claim 78 is dependent, discloses that during the second phase, the change induced during the first phase is removed. It is unclear how the change can be removed if it has not yet been induced.

Claims 100 and 110 each recite the limitation "a method for noninvasively determining at least one of a pulmonary capillary blood flow and a cardiac output of a patient". However, the claims, as recited, fail to provide steps of actually determining such parameters.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 34, 35, 38-40, 44, 45, and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Mault et al. Mault discloses a Fick technique of determining cardiac output comprising a step of evaluating respiration of a patient during a first ventilation state (normal breathing) for a period of 2 to 3 minutes, immediately followed by a step of evaluating respiration of the patient during a second ventilation state involving an increase or decrease of FIO₂ for a duration of 30 to 50 seconds (figure 2, col. 6, lines 8-65).

The specification of the instant application states "The first and second phases, or ventilation states, of the inventive differential Fick technique may be effected for substantially the same amount of time, meaning that, while the first and second phases may have exactly the same duration . . . one of the phases may alternatively be somewhat longer than the other." The specification further gives the example that either the first or second phase of may comprise as little as about 30% of the combined duration of the first and second phases or as much as about 70% of the combined duration of the first and second phases (see p.12, paragraph 0048 of the instant specification). In view of the applicants' description of effecting the first and second ventilation states for substantially the same amount of time, the periods described in Mault et al. qualify as being substantially the same. For example, if the first ventilation state lasted 2 minutes and the second ventilation state lasted 50 seconds, the first ventilation state would comprise about 70% of the combined duration of the two states

and the second ventilation state would comprise about 30% of the combined duration of the two states.

Claims 34-36, 39-41, 44, 45, 47, 52, 53, 58-61, 63, 64, 70, 77, 79, 84, 93, 94, 110, 113-115 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,200,271 to Kück et al. (herein referred to as Kück '271). Kück '271 discloses a method of bi-directional rebreathing in which the patient's respiratory carbon dioxide and flow are monitored during each of three phases. The three phases are comprised of a "before" rebreathing phase, lasting an average of 43 seconds, a "during" rebreathing phase lasting about 50 seconds, and an "after" rebreathing phase, having a duration long enough to facilitate the accurate determination of $\dot{V}CO_2$ and $C_A CO_2$. These measurements are then used to determine pulmonary capillary blood flow or cardiac output according to a differential Fick technique (figs. 2, 3)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 34-36, 43-45, 47, 52, 63, 64, 70, 77, 79, 84, 93, 94, 110, 113-115 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,540,689 to Orr et al. (herein referred to as "Orr '689"). Orr '689 discloses a differential Fick technique, comprising a first phase in which respiratory flow and carbon dioxide pressure data are

obtained over time periods before rebreathing, during a change (rebreathing) in the effective ventilation of a patient is induced, and during stabilization, or after said change is removed. The method employs a best-fit line method of rebreathing and a bi-directional rebreathing cycle (figs. 3A-D, col. 7, line 30-col. 10, line 65).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,517,496 to Mault. Mault fails to disclose maintaining the first ventilation state for about 30 seconds or maintaining the combination of the first and second ventilation state for about two minutes.

At the time of invention it would have been an obvious matter of design choice to a person of ordinary skill in the art to alter the length of either ventilation states such that the first ventilation state lasts about 30 seconds or the combination of ventilation states

lasts 2 minutes overall because the applicants have not disclosed that effecting the ventilation states for the given amount of time provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicants' invention to perform equally well with either the durations taught by Mault or the claimed 30 second duration of the first ventilation state and the 2 minute overall duration of the combined ventilations states because both sets of durations sufficiently allow measurement of the cardiac output of the patient. Therefore, it would have been obvious matter of design choice to modify Mault et al. to obtain the invention as specified in claims 37 and 41.

Claims 37, 38, 54-57, 71-74, 76, 88-92, and 112 are rejected under 35 U.S.C. 103(a) as being obvious over Kück '271.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer

in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Kück '271 fails to disclose specific duration of the "after" rebreathing phase either by a given period of time or in reference another phase and further fails to define any of the phases as having a duration of 30 seconds. Because the applicants have not disclosed that any specific length of any of the ventilation phases provides an advantage, is used for a particular purpose, or solves a stated problem, at the time of invention, it would have been an obvious matter of design choice to a person of ordinary skill in the art to set the length of any of the ventilation states such that a) any of the ventilation states are effected for about 30 seconds, b) any of the ventilation states are effected for at least about 30% of the combined duration of two of the phases, and/or c) the combined duration of two phases are about 2 minutes. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the ventilation states as described by Kück '271. Accordingly, the specified durations of the ventilation states, either individually or combined, as specified in claims 37, 38, 54-57, 71-74, 76, 88-92, and 112 are deemed to be obvious design considerations which fail to patentably distinguish over the prior art of Orr '689.

Allowable Subject Matter

Claim 100 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Claims 42, 46, 48-51, 61, 62, 65-69, 78, 80-83, 85-87, 95-99, 101-109, 111, and 116-120 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 42 and 61, the prior art of record fails to teach a method of estimating pulmonary capillary blood flow or cardiac output comprising the steps of evaluating respiration during a first ventilation state, which comprises bi-directional rebreathing, and evaluating respiration during a second ventilation state. Bi-directional rebreathing is defined by the instant specification on pp. 15-16, paragraph 0061.

Regarding claims 46, 49-51, 65, 67-69, 78, 81-83, 95, 97-99, 116, and 118-120, the prior art fails to teach or fairly suggest a method for estimating pulmonary capillary blood flow or cardiac output comprising a step of optimizing a duration of at least a first or a second ventilation state. Optimization of a duration is described by the instant specification on pp. 12-13, paragraph 49.

Regarding claims 48, 66, 80, 96, and 117, the prior art of record fails to teach or fairly suggest a method of determining pulmonary capillary blood flow or cardiac output comprising effecting two ventilation states wherein the transition between the states is

gradual. A gradual transition between two ventilation states is described in the instant specification on p. 12, paragraph 47.

Regarding claim 62, the prior art of record fails to teach a method for estimating pulmonary capillary blood flow or cardiac output comprising the steps of evaluating respiration during a first ventilation state, which employs a best-fit line method of rebreathing, evaluating respiration during a second ventilation state immediately following the first ventilation state, and evaluating respiration of the patient during another first ventilation state immediately following the second ventilation state.

Regarding claim 75, the prior art of record fails to teach or fairly suggest a differential Fick technique comprising a first phase inducing an effective ventilation change, a second phase removing the change, and repeating the first and second phases in immediate sequence with one another.

Regarding claims 85-87, the prior art of record fails to teach or fairly suggest a differential Fick technique comprising the steps of inducing a change in effective ventilation for a first duration of time, removing said change for a second duration immediately following the first duration, and repeating said inducing immediately following said second duration of time. The prior art further fails to teach obtaining measurements of at least one respiratory gas and of respiratory flow during all three durations of time.

Regarding claims 100-109, and 111, the prior art of record fails to teach or fairly suggest a method of determining at least one of pulmonary capillary blood flow and cardiac output comprising the steps of inducing a change in effective ventilation of a

patient for a first period of time, removing said change for a second period of time immediately following the step of inducing, and repeating the step of inducing immediately following the second period of time.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,413,226 to Starr et al.

US Patent No. 6,258,038 to Haryadi et al.

US Patent No. 6,238,351 to Orr et al.

US Patent No. 6,210,342 to Kück et al.

"Noninvasive cardiac output measurement in orthostasis: pulse contour analysis compared with acetylene rebreathing" by Stok et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Mon-Fri 9:30 am-7:00 pm (alternate Fri. off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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